

REMARKS

In response to the Office Action, claims 1-5 and 10-12 have been canceled. Such cancellation is without prejudice to further prosecution of these claims in one or more continuing applications. Claims 6, 13 and 16 have been amended. Claims 17-19 have been added.

Claim 6 has been amended to now specify that the first flexible strap and second flexible strap are separate, i.e., isolated straps, and not connected until acting as a wound closure device. Support for this can be found in the specification, particularly at Figure 1 and in paragraphs 0024 and 0025 of the published patent application. In addition, claim 6 has been amended to incorporate the language recited in now canceled claim 15. No new matter has been added by the amendments to claim 6. Claims 13 and 16 have been amended to correct dependency.

Dependent claim 17 has been added. Claim 17 is directed to the concept of the ratcheted teeth on the male end of the first strap. Support for this claim is found in the specification on page 2, paragraph 0024 of the published patent application.

Newly added claims 18 and 19 are directed to a method for closing a wound and recite use of the claimed invention. Support for these claims may be found in the specification at pages 3 and 4, paragraphs 0033 and 0034 of the published patent application.

The Abstract has been amended pursuant to the Examiner's instructions.

No new matter is added. Favorable reconsideration is respectfully requested. The following comments address the issues presented in the Office Action dated February 17, 2006 in order of their appearance in the Office Action.

The Abstract

Pursuant to the Examiner's suggestions and instructions, the Abstract has been amended to clarify the invention and remove language more suitable for the claims.

Claim Rejections - 35 USC § 102

Claims 1-14 have been rejected under 35 USC § 102(b) over U.S. Patent 5,584,859 to *Brotz*.

Claims 1-5 and 10-12 have now been canceled. Turning to claim 6, the Examiner states that *Brotz* teaches a wound closure device for connecting tissue (10) comprising a first flexible

strap (14) having a proximal end (46) and a distal end, and a ventral surface and a dorsal surface. The Examiner notes that any strap inherently comprises a proximal and distal end and a ventral and dorsal surface. The device is further alleged to include a second flexible strap (15) having a proximal end (48) and a distal end, and a ventral surface and dorsal surface, wherein the proximal end terminates in a connector (12) designed and configured to adjustably connect to the proximal end of the first strap (46), wherein the first strap and the second strap have at least one barb (16) on the ventral surface for engaging the tissue; whereby the straps form a wound closure. In view of the amendments to claim 6, this amendment is respectfully traversed.

The invention now recited in claim 6 is directed to at least one pair of isolated first and second flexible straps. In other words, the straps are separate from each other prior to engagement as a wound closure device. The first flexible strap has a proximal “male” connector end and at least one barb on the ventral surface for engaging the tissue. The second flexible strap has a proximal “female” connector end and at least one barb on the ventral surface for engaging the tissue. The female connector is configured to adjustably connect to the male connector of the first strap to form the wound closure. This wound closure process is adjustable. In other words, the adjustment can be tight or loose depending on the tension of the connection between the male and female connectors. *Brotz* neither discloses nor suggests the recited invention.

Referring to the Examiner’s description of *Brotz* in the later described rejections under 35 USC § 103 (at page 6 of the Office Action), the Examiner states that *Brotz* “teaches all aspects of the preceding claim 10 as described previously, but fails to disclose the device wherein the proximal end of the first strap comprises a male end and the proximal end of the second strap comprises a female end comprising a buckle.” In view of this admission, applicant submits that claim 6 is now in allowable condition over *Brotz*. Further, there is no disclosure nor any suggestion in *Brotz* of a wound closure device comprising separate “male” and “female” ends as recited in claim 6. The “straps” referred to in *Brotz* are only part of a whole, single device. This device, once constructed, essentially becomes a frame for immobilizing the wound tissue. It encompasses two wound closure straps and a center body in one piece for holding the straps in place. The center body member 12 is necessary and integral to the closure device in *Brotz*. It is neither disclosed, suggested nor needed in the claimed invention. For these reasons, applicant respectfully submits that claim 6 is neither disclosed nor suggested by *Brotz*.

Claims 7-9 are also rejected as being anticipated by *Brotz*. In view of applicant's remarks above with respect to claim 6, from which claims 7-9 depend, it is now respectfully submitted that claims 7-9 are also in condition for allowance. Claim 13 now depends from claim 6. In view of applicant's amendment to claim 6, it is now respectfully submitted that claim 13 is also in condition for allowance.

Claim Rejections - 35 USC § 103

Claims 15 and 16 were rejected under 35 USC § 103(a) over the '859 patent to *Brotz* in view of U.S. Patent 4,730,615 to *Sutherland et al.*

In view of the cancellation of claim 15 and the amendment of claim 16 to now depend from claim 6, it is now believed that claim 16 is in condition for allowance. Notification of the same is respectfully requested.

Further, applicant believes that the combination of *Brotz* and *Sutherland et al.* is misplaced. *Sutherland et al.* describes a sternum closure device with a head portion, a tail portion and a flexible spine portion. The device appears most like a garbage bag closure device, sometimes commonly known as a zip-tie. *Sutherland et al.* is directed to a single device whereby the distal tail is threaded through the sternum and brought back to the proximal head. The tail passes through the head and is locked in place by serrations on the spine engaging a tang in the head portion. The tail is covered in stainless steel to assist in the piercing of the sternum and threading back to the head portion. The spine and the head are made of a biocompatible polymer. While both inventions may be considered to be in the medical device field, the inventions have two distinct purposes and can only be regarded as nonanalogous art. *Brotz* is used to suture skin and *Sutherland et al.* is only meant to suture the sternum. Further, because *Sutherland et al.* comprise a single piece, it does not follow that someone could modify the *Brotz* invention by simply adding the buckle from the *Sutherland et al.* invention. To do so would ultimately change the entire nature and substance of the *Brotz* invention. It is a basic tenet of the law of obviousness that the prior art must provide some kind of motivation for a skilled artisan to select, combine and/or modify features of references to render an invention obvious (MPEP 2143). If there is no such motivation to support the selection, combination and/or modification, the obviousness rejection is made in hindsight and must be withdrawn. Here, *Brotz* provides a single piece wound

closure device comprising a center member 12 connected to one or more pairs of wound closure devices. The center member 12 and the elastic connectors 22 are the connectors for the lateral members in *Brotz*. *Brotz* neither discloses nor suggests any other means of connecting the lateral members. Applicant submits that the only way the Examiner could have decided that the center member 12 could be replaced by male and female connector ends would have been after a review of applicant's invention, which is impermissible hindsight. In view of this, applicant respectfully submits that claim 16 is in allowable condition. Withdrawal of the rejection is respectfully requested.

New Claims

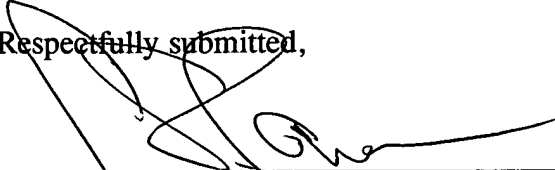
Claims 17-19 have been added. Claim 17, which depends from claim 16, recites the concept of a ratcheted surface in the male end of the first strap to accommodate the buckle of the female end. In view of applicant's remarks above, it is now believed that this claim is in allowable condition.

Claim 18 is directed to a method for closing a skinned wound with the wound closure device recited in claim 6. In view of applicant's remarks above, it is respectfully submitted that claim 18 and dependent claim 19 are in condition for allowance. Notification of the same is respectfully requested.

CONCLUSION

Applicant submits that the application is now in condition for allowance. Early notification of such action is earnestly solicited. Should the Examiner have any questions or comments with respect to the application, the Examiner is requested to contact the undersigned attorney. The attorney welcomes and encourages telephone calls related to this application because this may allow the resolution of any disputed claim language and/or other informalities more rapidly and efficiently than by any other means. The Commissioner is authorized to charge any fees or credit any overpayments relating to this application to deposit account number 18-2055.

Respectfully submitted,



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